CLINICAL RESEARCH PROTOCOL **CONTINUING** REVIEW APPLICATION	PROTOCOL NO.	PRINCIPAL INVESTIGATOR (Name, Institute/Branch, Address, Telephone):

PROTOCOL TITLE:

PROTOCOL STATUS:
☐ Renew -Recruitment of participants has not yet begun.
☐ Renew -Participants are currently being recruited or enrolled.
☐ Renew -No longer recruiting or enrolling participants, follow-up only.
☐ Renew -Enrollment complete; study and data analyses ongoing.
☐ Renew -Clinical Hold/Recruitment or enrollment of participants suspended.
☐ Terminate -Study closed. Recruitment and data analysis complete.

SUMMARY OF PROTOCOL ENROLLMENT (Aggregate): *When NIH is the coordinating site, provide enrollment table for each site.

NIH Site	Other Sites	Total	
			Accrual ceiling by IRB
			Aggregate total reported w/ last CR
			New subjects accrued since last CR
			Aggregate total accrued*

*(If accrual has been less than expected, discuss in the attached narrative.)

REQUESTED ACCRUAL EXCLUSION (Check all that apply):
☐ None ☐ Asian
☐ Male ☐ Black or African American
☐ Female ☐ White
☐ Children <18 ☐ Hispanic or Latino
☐ American Indian/ Alaskan Native ☐ Native Hawaiian or Pacific Islander
☐ Other: _____

ARE YOU CURRENTLY RECRUITING HEALTHY VOLUNTEERS? ☐ No ☐ Yes

PHASE 3 CLINICAL TRIALS WHICH HAVE COMPLETED RECRUITMENT MUST REPORT SEX, RACIAL/ETHNIC ANALYSIS AS REQUIRED BY THE NIH POLICY AND GUIDELINES ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH.

Have analyses by sex, racial/ethnic subgroups been conducted?
☐ No ☐ Yes (answer a and b)
a. Have analysis been reported? ☐ No (explain in narrative) ☐ Yes
b. Have significant differences been found? ☐ No ☐ Yes

HAVE ANY NON-NIH INVESTIGATORS OR SITES BEEN ADDED SINCE THE LAST REVIEW?
☐ No
☐ Yes (Identify the persons or sites and describe the collaboration in the summary report)

WITH THIS REVIEW, I AM REQUESTING A CHANGE TO THE FOLLOWING:
PRINCIPAL INVESTIGATOR:
Delete: _____
Add: _____

ASSOCIATE INVESTIGATORS?
☐ No ☐ Yes (Identify in the attached narrative.)

LEAD ASSOCIATE INVESTIGATOR:
Delete: _____
Add: _____

MEDICAL ADVISORY INVESTIGATOR:
Delete: _____
Add: _____

RESEARCH CONTACT:
Delete: _____
Add: _____

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET, etc.):
☐ None
☐ Medically indicated
☐ Research indicated
☐ Research usage HAS NOT changed.
☐ Research usage HAS changed. (Explain in summary report)

INVESTIGATIONAL NEW DRUG/DEVICE: ☐ None ☐ IND ☐ IDE

FDA No. _____
Name: _____
Sponsor: _____
Who is the manufacturer of the above entity? _____

DOES THE PROTOCOL INVOLVE A DRUG/DEVICE/PRODUCT THAT MAY LEAD TO YOU OR THE NIH RECEIVING PAYMENT AND/OR ROYALTIES?
☐ No
☐ Yes*(Append a statement of disclosure)

HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?
☐ No
☐ Yes (Describe in Summary report)

HAS THE NIH IRP COI GUIDE BEEN DISTRIBUTED TO NON-NIH INVESTIGATORS?
☐ No
☐ Yes

BASED ON THE CRITERIA AT THEIR INSTITUTION, HAS A CONFLICT BEEN REPORTED?
☐ No conflicts reported.
☐ Yes, conflict(s) reported. Describe in attached narrative.

CONFLICTS OF INTEREST REVIEW?
Date submitted to IC DEC:_____ Date cleared by IC DEC:_____

THE FOLLOWING ELEMENTS ARE REQUIRED IN THE ATTACHED SUMMARY REPORT ALONG WITH THE PROTOCOL, CONSENT DOCUMENT(S) AND SUMMARY OF FDA ANNUAL REPORT, IF APPLICABLE:

1) a brief narrative explaining current progress/finding from the research;
2) a summary of any amendments made to the research protocol since the last CR:
3) the number of subjects accrued, including a demographic table and a description of any changes in the subject population, recruitment or selection criteria;
4) a summary of adverse events and any unanticipated problems involving risks to subjects or others;
5) a summary of subject withdrawals from the research;
6) any reports of complaints about the research since the last IRB review;
7) any relevant multi-center reports;
8) any data and safety monitoring board reports;
9) any information from the literature or from this or similar research that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved; and
10) reason(s) for continuing the study.

SIGNATURE	_____ Principal Investigator	_____ Print/Type Name	Date _____	Send to Accountable Investigator
RECOMMENDATION	_____ Accountable Investigator	_____ Print/Type Name	Date _____	Send to Branch Chief, or CC Dept. Head of Accountable Investigator
	_____ Br Chief/CC Dept. Head of Acct. Invest	_____ Print/Type Name	Date _____	Send to Clinical Director
APPROVALS	_____ Clinical Director	_____ Print/Type Name	Date _____	Send to Chair, Institutional Review Board
	_____ Chair, For Institutional Review Board	_____ Print/Type Name	Date _____ Protocol & Consent Approved Effective	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	_____ Protocol Specialist	Date _____		